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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,944

02/26/2004

William R. Patterson

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05/28/2008

FOLEY & LARDNER LLP
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,944	Applicant(s) PATTERSON ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9-13,15,16,36,38-44,46,47 and 51-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,9-13,15-16,36,38-44,46-47,51-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/25/2008 has been entered. Applicants amendments to the claims filed 04/25/2008 have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 recites the limitation "wherein at least about 25% of the surface hydroxyl groups" in line 3 of page 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 1618

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7,9-13,15-16,36,38,41-44,46-47,51-52 and 53 are rejected under 35

U.S.C. 102(e) as being anticipated by Porter et al. (US 2004/0156781 A1), cited previously.

Porter teaches polymer-embolizing compositions for filling cavities of the body and kits comprising such compositions. See abstract. The composition comprises a polymer (preferably EVOH), contrast agent (including tantalum), rheological modifier (preferably fumed-silica) and solvent (preferably DMSO). See [0062],[0067],[0074],[0079],[0091],[0096] and claims 1-7,10-19. The amount of rheological modifier was sufficient to permit the composition to exhibit thixotropic behavior, permitting the compositions to exhibit high viscosities under static conditions while maintaining excellent flow properties under stress. See [0003]. Regarding the limitation that the embolic composition is sterilized, it is inherent that since the compositions of Porter are administrable by catheter into the body they would be sterile. The examiner did not give patentable weight to the recitation that the composition was sterilized by irradiation, since the composition is the same the product to produce it including its sterilization process does not lead to a patentable difference between applicants claimed invention and the prior art. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different

Art Unit: 1618

process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 7,9-13,36,38,41-44,46-47 and 53 since the claimed composition is not patentably distinct from the Porter patent and the compositions as currently claimed are the same they will have the same shelf life characteristics such as viscosity change over a period of time, the compositions will have the same viscosity and the same shear rate.

Regarding claim 36, Porter claims the use of caroxymethylcellulose and methylcellulose, it is inherent that since each saccharide unit must contain at least one methyl or carboxymethyl group formed from reaction with an open hydroxyl group that at least 33% of the cellulose's OH groups have been converted to non hydroxyl groups since there is only three open hydroxyl groups on each saccharide monomer ($1/3 = 33\%$).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7,9-13,15-16,36,38-44,46-47,51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (US 2004/0156781 A1) in view of Reagan (US 5,472,493).

Porter is disclosed above. Porter does not disclose the use a rheological modifier that contains greater than 33% of surface hydroxyl groups that are converted to non-hydroxyl groups as required within claims 39 and 40. Porter also does not disclose the use of fumed silica wherein at least 25% of the surface hydroxyl groups have been converted to non-hydroxyl groups as required within claim 54.

Reagon is used only for the disclosure within the background information of the reference that treated fumed silica such as CAB-O-SIL TS-720 was already well known to be used as an agent to improve rheology. See col 1 lin 12-42. CAB-O-SIL TS-720 was described by applicants specification [0251] as a commercially available silica which has been surface treated to provide for essentially no surface silanol groups. The advantageous of using the treated fumed silica as described within Reagan is that it

Art Unit: 1618

exhibited improved flow control and storage stability for a composition. One of ordinary skill in the art would have a high expectation of success in adding/substituting CAB-O-SIL TS-720 for the rheological compounds of Porter since both compounds are fumed silicas that are added to compositions to improve rheology, thus the compounds are similar structurally and they are usefull in the same field of endeavor. One of ordinary skill in the art would have been motivated to combine/substitute the CAB-O-SIL TS-720 for the fumed silica of Porter since the treated silica had several disclosed advantageous such as improved flow control and storage stability that would obviously be beneficial for a composition such as an embolic composition that would be stored for an indefinite period of time before use. Thus applicants claimed invention would have bee prima fascia obvious in view of the combined prior art references above.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1618

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618